Docket No.: 10086/2 (14420-00004-US) (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Richard J. Riehle et al.

Application No.: 10/013,049

Confirmation No.: 2668

Filed: December 10, 2001

Art Unit: 1744

For: REDUCED BYPRODUCT HIGH SOLIDS

POLYAMINE-EPIHALOHYDRIN

COMPOSITIONS

Examiner: W. H. Beisner

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MS Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Appellants hereby appeal the Examiner's decision rejecting claims 1-13, 15-21, and 35-38, as set forth in the Office Action of December 13, 2006.

As required under 37 C.F.R. § 41.37(a)(1), this brief is filed within two months from the date of filing of the Notice of Appeal, which was filed on March 9, 2007.

I. REAL PARTY IN INTEREST

The real party in interest is Hercules Incorporated (hereinafter "Hercules"). Hercules acquired the entire rights in the application by assignment from the inventors, which was recorded on March 22, 2002 at Reel/Frame 012766/0143.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other prior or pending appeals, interferences, or judicial proceedings of which the Appellants are aware that are related to or will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-13, 15-21, and 35-38 are presently pending and stand rejected. Claim 30 was cancelled in an amendment filed June 2, 2004. Claim 14 was cancelled in an amendment filed April 14, 2006. Claims 22-29, 31-34 and 39 were cancelled in an amendment filed April 20, 2007. The claims on appeal are claims 1-13, 15-21, and 35-38, which are reproduced in Appendix A.

IV. STATUS OF AMENDMENTS

Appellants filed an amendment after final rejection on April 20, 2007 to cancel claims 22-29, 31-34, and 39 without prejudice to pursuing such claims in a continuing application. This amendment is currently under consideration by the Examiner.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Of the 24 claims on appeal, only claims 1 and 36 are independent.

Claim 1 recites a process for rendering a polyamine-epihalohydrin resin storage stable. This process comprises the step of treating a composition containing a polyamine-epihalohydrin resin and comprising a CPD-forming species and having a solids content of at least 15 wt% with at least one enzymatic agent under conditions to at least one of (i) inhibit, (ii) reduce and (iii) remove the CPD-forming species to obtain a gelation storage stable reduced CPD-forming resin. The composition containing the reduced CPD-forming polyamine-epihalohydrin resin, when stored for 24 hours at 50 °C and a pH of about 1.0, releases less than about 100 ppm dry basis of CPD. *See* present specification at page 8, lines 4-6 and line 30 to page 9, line 18; page 10, lines 14-28; page 11, lines 1-12; page 17, line 22 to page 18, line 1; and page 120, lines 1-13. The polyamine-epihalohydrin resin of the composition to be treated by this process is formed in a

reaction having a molar ratio of epihalohydrin to secondary amine group of less than 0.50. See present specification at page 24, lines 10-14. The solids content of the composition to be treated by this process is at least 15 wt% when treated with the at least one enzymatic agent. See present specification at page 10, lines 20-28. The at least one enzymatic agent used in this process is selected from the group consisting of an esterase, a lipase, a protease or a combination thereof. See present specification at page 9, lines 3-18.

Claim 36 recites a process for preparing a paper product. This process comprises two steps:

- (1) treating a composition containing a polyamine-epihalohydrin resin and comprising a CPD-forming species and having a solids content of at least 15 wt% with at least one enzymatic agent under conditions to at least one of (i) inhibit, (ii) reduce and (iii) remove the CPD-forming species to obtain a gelation storage stable reduced CPD-forming resin (*See* present specification at page 8, lines 4-6 and line 30 to page 9, line 18; page 10, lines 14-28; page 11, lines 1-12; page 17, line 22 to page 18, line 1; and page 120, lines 1-13); and
- (2) forming a paper product with the reduced CPD-forming polyamine-epihalohydrin resin, so that the paper product contains less than about 250 ppb of CPD when corrected for adding at about a 1 wt% addition level of the reduced CPD-forming resin. *See* present specification at page 19, line 18 to page 20, line 14; page 30, line 4 to page 31, line 19; and page 120, lines 28-30.

The polyamine-epihalohydrin resin of the composition to be treated by this process is formed in a reaction having a molar ratio of epihalohydrin to secondary amine group of less than 0.50. See present specification at page 24, lines 10-14. The solids content of the composition to be treated by this process is at least 15 wt% when treated with the at least one enzymatic agent. See present specification at page 10, lines 20-28. The at least one enzymatic agent used in this process is selected from the group consisting of an esterase,

a lipase, a protease or a combination thereof. *See* present specification at page 9, lines 3-18.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole ground of rejection for review on appeal is the rejection of claims 1-13, 15-21, and 35-38 under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner contends that these process claims allegedly do not include an additional step deemed critical or essential to their practice. Appellants respectfully disagree.

VII. ARGUMENT

Claims 1-13, 15-21 and 35-38

Independent claims 1 and 36 and dependent claims 2-13, 15-21, 35, 37, and 38 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner contends that these claims are not enabled by the specification disclosure because they do not include an additional step of contacting the composition with at least one microorganism, or least one enzyme located from the at least one microorganism, in an amount and at a pH and temperature effective to dehalogenate residual quantities of organically bound halogen (hereinafter referred to as a "biodehalogenation step"). (See Office Action of December 13, 2006, page 5). The Examiner concludes that a biodehalogenation step is critical to practice the claimed invention with reference to three of the 38 examples from the present specification. The Examiner states that (1) only Examples 3, 24 and 25 are drawn to enzyme treatment of a starting composition with a solids content of at least 15% by weight that establishes that the treated composition releases less about 100 ppm dry basis of CPD when subjected to the "ACID TEST" (i.e., when stored for 24 hours at 50 °C at a pH of about 1.0), and (2) Examples 3, 24 and 25 all employ a biodehalogenation step. (See Office Action of December 13, 2006, pages 2-5). Appellants disagree that any such additional step is necessary to practice the claimed invention and respectfully traverse this rejection.

The Examiner errs by referring only to three examples without considering and giving weight to the entirety of the specification disclosure. In determining whether an

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unclaimed feature is critical, the entire disclosure must be considered. See In re Goffe, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976); see also MPEP § 2164.08(c). Thus, the entire contents of the present application must be taken into consideration to determine whether an additional biodehalogenation step is critical to practicing the claimed process. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality. Id. Furthermore, features that are merely preferred are not to be considered critical. Id. Section 2164.08(c) of the MPEP additionally states that "[a]n enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended."

The specification of the present application does not state that a biodehalogenation step, or any other additional step, is critical to practice the claimed process. To the contrary, the specification clearly discloses that no additional step is necessary to practice the claimed process. The present specification states at page 15, line 27 to page 16, line 2 that "[t]he enzyme treatment can be applied on resins as produced in a resin synthesis process without further treatment." This same section of the specification also discloses that the resins can be (i.e., may optionally be) treated (i) before, (ii) after or before and (iii) after the enzyme treatment by various other processes. The present specification also distinguishes between the levels of CPD that may be released and/or produced by the resin where the enzyme treatment is applied without need for further treatment (page 17, line 22 to page 18, line 8) and where an additional treatment is applied prior to, subsequent to or simultaneously with the enzyme treatment (page 18, lines 9-27). The present specification at page 31, line 20 to page 32, line 15 reiterates that the enzyme treatment can be applied to resins without further treatment and that such further treatment (i) before, (ii) after or before and (iii) after the enzyme treatment is optional. Thus, the specification of the present application contains specific language disclosing that no additional step, biodehalogenation or otherwise, is necessary to practice the claimed process. This language cannot be ignored.

The Examiner acknowledges this language in the specification is there, but nonetheless maintains that an additional biodehalogenation step is critical to practicing the claimed invention. (*See* Office Action of December 13, 2006, pages 6-7, paragraph 4). The Examiner asserts that if the biodehalogenation step was not critical, then those examples in the present specification directed to enzyme-treated compositions having at least 15 weight % solids content, but which were not further treated with a biodehalogenation step (i.e., Examples 2, 6-19, and 31), would have released less than about 100 ppm dry basis of CPD when subjected to the ACID TEST. *Id.* However, as the Examiner notes, none of these Examples disclose ACID TEST data. *Id.* As such, the Examiner's conclusion that an additional biodehalogenation step is critical to achieving a CPD release of less than about 100 ppm dry basis during the ACID TEST is improper. The Examiner assumes that if Acid Test data had been reported for Examples 2, 6-19, and 31, such data would have been greater than about 100 ppm. Such assumption is not proper.

The Examiner also assumes that, in Examples where resin is treated with enzyme followed by biodehalogenation (*See, e.g.*, Examples 2 and 3 at page 42, line 19 to line 44, line 4; Example 24 at page 70, line 21 to page 73, line 20), the ACID TEST data of less than about 100 ppm dry basis of CPD could not be attributable solely to the enzyme treatment. *See* Table 1, page 44 and Table 11, page 73. However, Tables 1 and 11 both show that the release of CPD from the treated resins plateaus after 4 hours of enzyme treatment. This data can be alternatively interpreted to indicate that (1) the vast majority of CPD has been removed from the resin by enzyme treatment, resulting in a resin that produces less than about 100 ppm dry basis of CPD when subjected to the ACID TEST; and (2) the biodehalogenation step is simply removing enzyme-released CPD from the resin solution. As such, the Examiner's assumption is not proper.

The Examiner's rejection also implies that claims 1-13, 15-21, and 35-38 are not enabled unless the specification sets out an *example* illustrating that enzyme treatment alone of a composition with a solids content of at least 15% results in a treated composition releasing less than about 100 ppm dry basis of CPD when subjected to the ACID TEST. *See* Office Action of December 13, 2006, page 7. However, the

"specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation." See In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970); see also MPEP § 2164.02. In other words, as long as the scope of enablement provided by the specification to persons of ordinary skill in the art bears a reasonable correlation to the scope of the claims, the enablement requirement of 35 U.S.C. § 112, first paragraph, is met. See In re Fisher, 427 F.2d 833, 839 166 USPQ 18, 24 (CCPA 1970). Specific examples (data) are not required.

Processes encompassed by claims 1-13, 15-21, and 35-38 are disclosed in the present specification in such a manner that one skilled in the art is able to practice them without an undue amount of experimentation. See, generally, page 8, line 8 to page 41, line 25. Regarding enzyme treatment of the resin, the present specification teaches how reaction parameters, such as time, temperature, pH, and enzymatic agent concentration, can be varied to achieve certain desired properties in the enzyme-treated resin. See page 11, lines 1-12 and page 13, line 5 to page 15, line 26. In particular, the present specification teaches that "as the treatment time is increased, the amount of CPD released from the CPD-producing species is desirably increased, with a preferred treatment time being 6 to 10 hours." See page 13, lines 26-28. In other words, as enzyme treatment time is increased, the concentration of remaining CPD-producing species in the resin is decreased. This is supported by the data disclosed for Example 2 in Table 1 and Example 24 in Table 11 in the present specification, which shows that as enzyme treatment time increased, so did the amount of CPD released, with the amount of CPD released peaking after 4 hours of treatment. See page 42, line 19 to page 44, line 4 and page 70, line 21 to page 73, line 20. In turn, further decreases in concentration of remaining CPD-producing species in the resin results in lower concentrations of CPD that can potentially be released when the composition is subjected to the ACID TEST. As such, the scope of enablement provided in the present specification to persons of ordinary skill in the art bears a reasonable correlation to the scope of claims 1-13, 15-21, and 35-38.

Appellants did not admit, as the Examiner contends, that "compositions with greater than 15 weight % involve unpredictable results." See Office Action of December

13, 2006, page 7. The Examiner previously asserted this alleged admission by Appellants in the Office Action of October 19, 2005, citing to page 9, lines 16-29 and page 40, line 27 to page 41, line 6 of the present specification for support. The passage at page 9, lines 16-29, when read in context, clearly pertains only to unexpected viscosity characteristics of polyamine-epihalohydrin resin containing compositions resulting from enzyme treatment under balanced treatment conditions and not to any unpredictability in the CPD release of such enzyme-treated resin. Likewise, the passage at page 40, line 27 to page 41, line 6 clearly pertains only to unexpected characteristics of the optional biodehalogenation step and not to any unpredictability in the CPD release of enzyme-treated resins. As such, Appellants have made no blanket admission in these passages regarding the unpredictability of compositions with greater than 15 weight %.

The present specification (1) does not specify that a biodehalogenation step, or any other additional step, is critical to practice the claimed process, and (2) unambiguously teaches that no additional step in necessary to practice the claimed process. Furthermore, processes encompassed by claims 1-13, 15-21, and 35-38 are disclosed in the present specification in such a manner that one skilled in the art is able to practice them without an undue amount of experimentation. Therefore, Appellants respectfully request that the enablement rejection under 35 U.S.C. § 112, first paragraph, of claims 1-13, 15-21, and 35-38 be reversed.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

No evidence submitted pursuant to 35 C.F.R. §§ 1.130, 1.131, or 1.132 is being relied upon for this appeal.

X. RELATED PROCEEDINGS

As stated in section II, *supra*, no related proceedings have been or are now pending. Accordingly, there are no related decisions to be provided.

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XI. <u>CONCLUSION</u>

For these reasons, reversal of the enablement rejection under 35 U.S.C. § 112, first paragraph, of claims 1-13, 15-21, and 35-38 is strongly urged.

The Director is authorized to charge \$500.00 to Deposit Account No. 03-2775, under Order No. 14420-00004-US, to cover the fee under 37 C.F.R. § 41.20(2) for this Appeal Brief. Appellants believe no additional fee is due. However, if any additional fee is due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 14420-00004-US, from which the undersigned is authorized to draw.

Dated: May 8, 2007

Respectfully submitted,

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